State of Maryland Department of Health & Mental Hygiene

Medwatch

Revised for submission of brand medically necessary requests for Maryland Pharmacy Program
Prescriber must have witnessed or has documentation that the manifestation of adverse event(s) is linked to generic drug.
Completion of form does not automatically grant approval; incomplete forms will be returned with denial.***

A. PATIENT INFORMATION

Name: _____ Sex ☐ F ☐ M

MA ID#: _____ DOB: _____/_____/_____

Weight _____lbs Phone #: (_____) _____

Has a generic been tried before? Yes_____ No_____

Give date: _____/_____/_____ Age at time of event: _____

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g. defects malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply.)*

☐ Death: _____
(mo/day/yr)

☐ Disability
☐ Life-threatening
☐ Congenital Anomaly
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Hospitalization–Initial or Prolonged

☐ Other:_____

3. Date of Event *(mo/day/yr)*	4. Date of This Report *(mo/day/yr)*

5. Describe Event or Problem; Relevant History & Tests

C. SUSPECT MEDICATION(S)

1. Name *(Give labeled strength & mfr./labeler, if known)*

#1 _____

#2

2. Dose, Frequency & Route Used	3. Therapy Dates
#1 _____	#1 _____
#2	#2

4. Diagnosis for Use *(Indication)*

#1 _____

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ N/A
#2 ☐ Yes ☐ No ☐ N/A

6. Lot # *(if known)*	7. Exp. Date *(if known)*
#1 _____	#1 _____
#2	#2

8. Event Reappeared After Reintroduction

#1 ☐ Yes ☐ No ☐ N/A
#2 ☐ Yes ☐ No ☐ N/A

9. NDC # *(specify generic manufacturer)*

D. DEGREE OF CERTAINTY THAT THE ADVERSE DRUG REACTION IS DUE TO GENERIC

___ **Definite.** The reaction follows a reasonable temporal sequence after generic drug exposure or a toxic blood level of the generic drug has been established in body fluids or tissue. The reaction follows a recognized response to the suspected generic drug. The reaction is confirmed by improvement on withdrawing the generic drug and reappears on re-exposure. "Other than drug causes" such as other drugs or toxins or concomitant disease states that can cause similar clinical reactions are ruled out.

___ **Probable.** The reaction follows a reasonable temporal sequence after generic drug exposure. The reaction follows a recognized response to the suspected generic drug. The reaction is confirmed by withdrawal but not by exposure to the generic drug. The reaction cannot be reasonably explained by known characteristics of the recipient's clinical state.

___ **Possible.** The reaction follows a temporal sequence after generic drug exposure. The reaction follows a possible recognized pattern to the suspected generic drug. The reaction could be explained by the recipient's clinical state (i.e. other than the suspected generic drug).

___ **Doubtful.** The reaction is likely to be related to factors other than the suspected generic drug.

___ **Negative.** The findings clearly eliminate the possibility of a drug reaction caused by the generic version of the drug.

List concomitant medications being taken by patient.

E. REPORTER

Prescriber's Name _____

Signature_____ DEA #_____

Address: _____

_____

Phone #: (_____) _____ -_____

Fax #: (_____) _____ -_____

Did the prescriber witness the ADR? ☐Yes ☐No

Has the ADR been previously reported to the FDA? ☐Yes ☐No

Please FAX form to the Maryland Pharmacy Program at 410-333-5398
DO NOT fax directly to the FDA